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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,842	10/26/2001	Michel J.N. Cormier	33392-754.201	2394
77069	7590	07/30/2008	EXAMINER	
Edwards Angell Palmer & Dodge LLP P.O. Box 55874 Boston, MA 02205			CAMERON, ERMA C	
ART UNIT	PAPER NUMBER			
			1792	
MAIL DATE	DELIVERY MODE			
			07/30/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/045,842	<b>Applicant(s)</b> CORMIER ET AL.
	<b>Examiner</b> /Erma Cameron/	<b>Art Unit</b> 1792

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 27 March 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 18-20,22-24,28-35,47 and 51-53 is/are pending in the application.

4a) Of the above claim(s) 28 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 18-20,22-24,29-35,47 and 51-53 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/28/2008

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### *Response to Amendment*

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

“...wherein the coating provides systemic delivery of about 25% to 50% of the agent upon application of the device to the skin of a subject for 5 seconds...” is new matter that was not in the specification as originally filed.

The specification does not support this statement as applied to all the active agents in the claimed invention.

[0061] [0064] [0066] [0071] and Figures 8-10 (cited by applicant for support) support:

[0061] 26% in 5 seconds for desmopressin

[0066] 50% in 5 seconds for hGH

[0071] >80% in 5 seconds for ovalbumin

The applicant is requested to cancel new matter.

3. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

See paragraph 2 above. 80% delivery in 5 seconds is not supported for all active agents in the claimed invention.

The applicant is requested to cancel new matter.

***Claim Rejections - 35 USC § 103***

4. *The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

5. The rejection of Claims 18-24, 29-35 and 47 under 35 U.S.C. 103(a) as being unpatentable over Szumski et al (3470011) is withdrawn because of the amendments and arguments presented in the 3/27/2008 amendment.

6. The rejection of Claims 18-24, 29-35 and 47 under 35 U.S.C. 103(a) as being unpatentable over Palmer (6537242) is withdrawn because of the amendments and arguments presented in the 3/27/2008 amendment.

7. The rejection of Claims 18-24, 29-35 and 47 under 35 U.S.C. 103(a) as being unpatentable over Powell (6589202) is withdrawn because of the amendments and arguments filed 3/27/2008.

8. The rejection of Claims 18-24, 29-35 and 47 under 35 U.S.C. 103(a) as being unpatentable over WO 96/10630 is withdrawn because of the amendments and arguments filed 3/27/2008.

9. The rejection of Claims 18-24, 29-35 and 47 under 35 U.S.C. 103(a) as being unpatentable over Ginaven et al (5457041) is withdrawn because of the amendment and arguments filed 3/27/2008.

10. The rejection of Claims 18-24, 29-35 and 47 under 35 U.S.C. 103(a) as being unpatentable over Cormier et al (US2002 / 010292) is withdrawn because of the statement of common ownership filed 3/27/2008.

***Double Patenting***

12. *The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

13. Claims 18-20, 22-24, 29-35, 47 and 51-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-64 of copending Application No. 11/034,891.

As outlined in the previous office action, although the conflicting claims are not identical, they are not patentably distinct from each other because the Application teaches the limitations of the claims and only fails to teach the dose, solubility, and viscosity of the agent of the instant claims. However, claims in the 11/034,891 application are directed to the same active agents as the claims and specification of the instant application, which would inherently be useful in the same dosage, solubility, and viscosity as instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 18-20, 22-24, 29-35, 47 and 51-53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-54 of

copending Application No. 10/127108, over claims 21-39 of copending Application No. 10/674626, over claims 10-13 of copending Application No. 10/972231, over claims 33-38 of copending Application No. 11/201625, over claims 32-34 of copending Application no. 11/206698 and over claims 30-35 of copending Application No. 11/355856.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the coatings on the microprotrusions of the Applications are merely variations of and included in the “pharmacologically active agent” of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. The applicant has asked that the double patenting rejections be stayed until subject matter is indicated to be allowable. This is being done.

***Declaration under 37 CFR 1.132***

16. The 1.132 Declaration under 37 CFR 1.132 filed 3/27/2008 is sufficient to overcome the rejection of claims 18-24, 29-35 and 47 based upon the prior art as indicated above.

***Conclusion***

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Erma Cameron/ whose telephone number is 571-272-1416. The examiner can normally be reached on Monday through Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Erma Cameron/  
Primary Examiner  
Art Unit 1792

July 21, 2008